(12) UK Patent Application (19) GB (11) 2 382 304 (13) A

(43) Date of A Publication 28.05.2003

(21) Application No 0124291.6

(22) Date of Filing 10.10.2001

(51) INT CL[7]
A61B 17/70

(52) UK CL (Edition V)
A5R RX7

(56) Documents Cited
GB 2269753 A
EP 0669109 A
WO 2002/102259 A2
WO 2001/045576 A1
US 5733284 A
US 5423816 A
US 5180393 A

(58) Field of Search
UK CL (Edition V) A5R
INT CL[7] A61B
Other: ONLINE: WPI, EPODOC, PAJ

(71) Applicant(s)
Dilip Kumar Sengupta
101 Delaunays Road, Crumpsall,
MANCHESTER, M8 4RE, United Kingdom

(72) Inventor(s)
Dilip Kumar Sengupta

(74) Agent and/or Address for Service
Forrester Ketley & Co
Chamberlain House, Paradise Place,
BIRMINGHAM, B3 3HP, United Kingdom

(54) Abstract Title
An assembly for soft stabilisation of vertebral bodies of the spine

(57) An assembly for soft stabilisation of vertebral bodies 12, 14 of the spine comprises a pair of pedicle screws 20 each having a threaded shaft 20a with a tapering first end 20b and a head portion 20c with a second end 20d; a helical spring member 18 having first and second ends; and a pair of fixation mechanisms (26, fig 3a) for securing the first and second ends of the helical spring member to the pair of pedicle screws. The helical screw member may be made from titanium or stainless steel wire and may further include a plastic sleeve (18c, fig 2a) covering the spring member. The assembly may further comprise an elastic member (60, fig 9) securable to the head ends of a pair of pedicle screws. Another embodiment also shows an assembly where the elastic member has been substituted for the helical spring member.

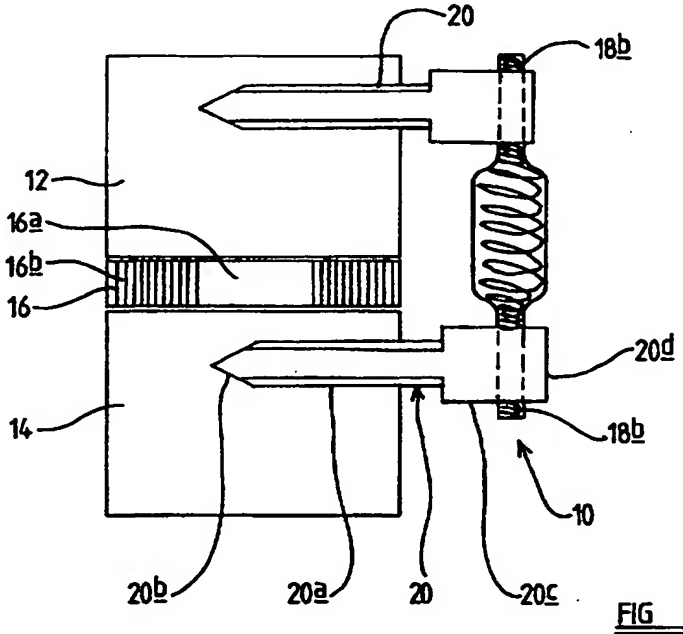

FIG 1

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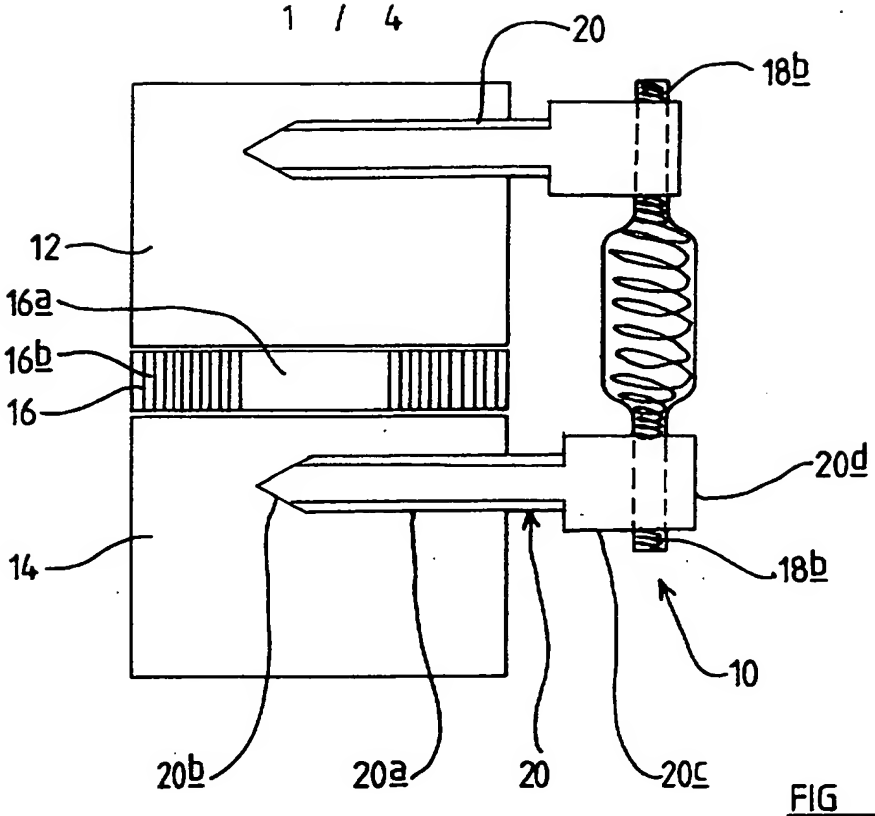


FIG 1

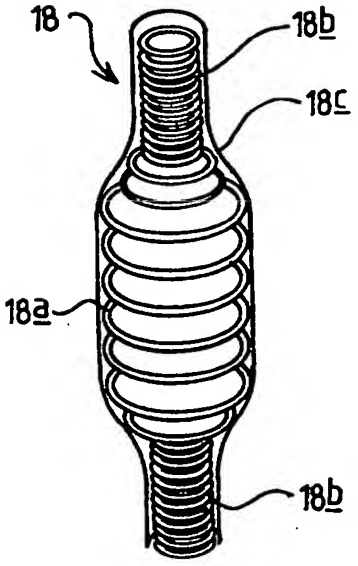


FIG 2a

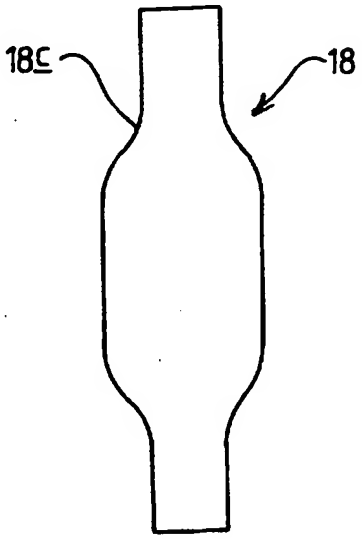


FIG 2b

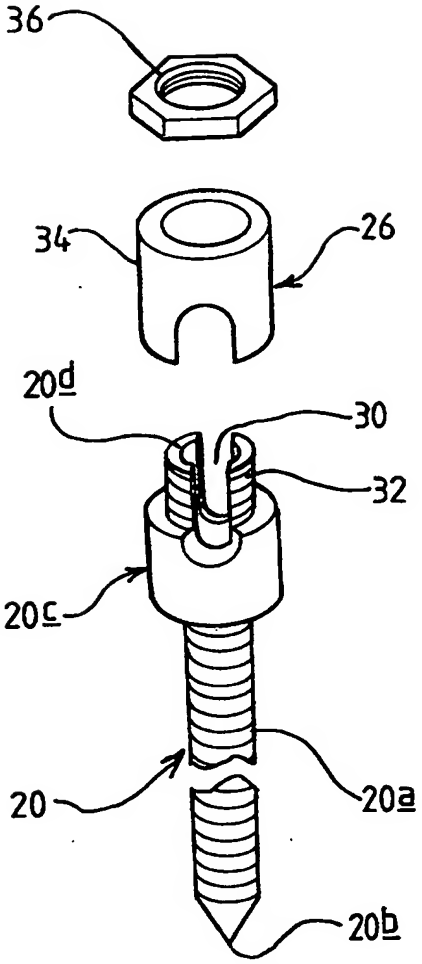


FIG 3a

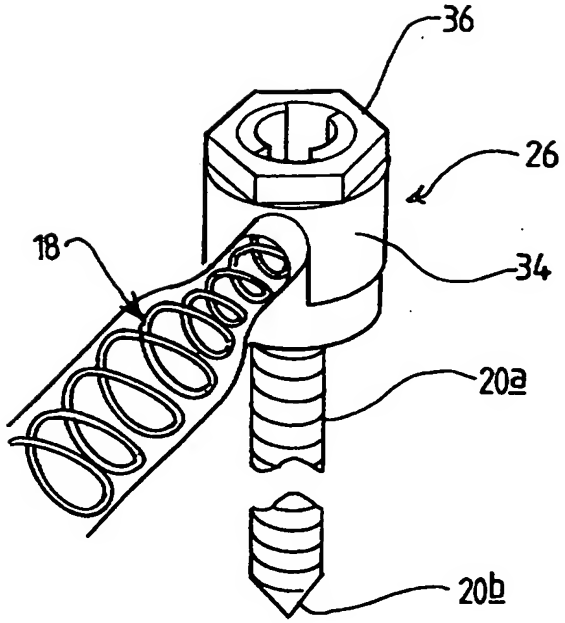


FIG 3b

FIG 4a

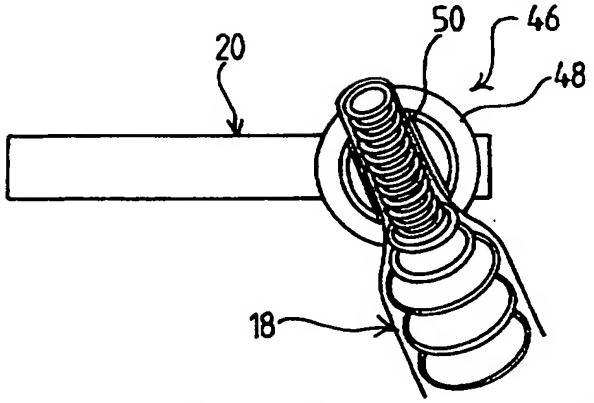
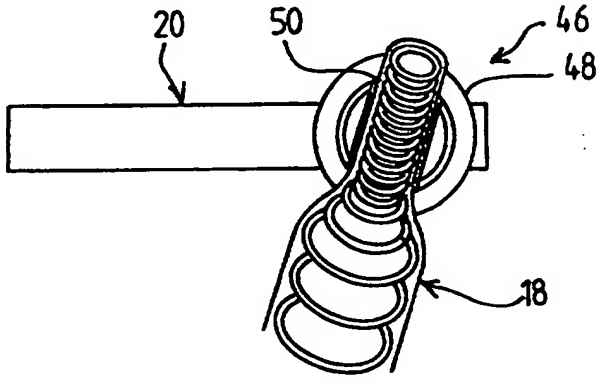


FIG 4b



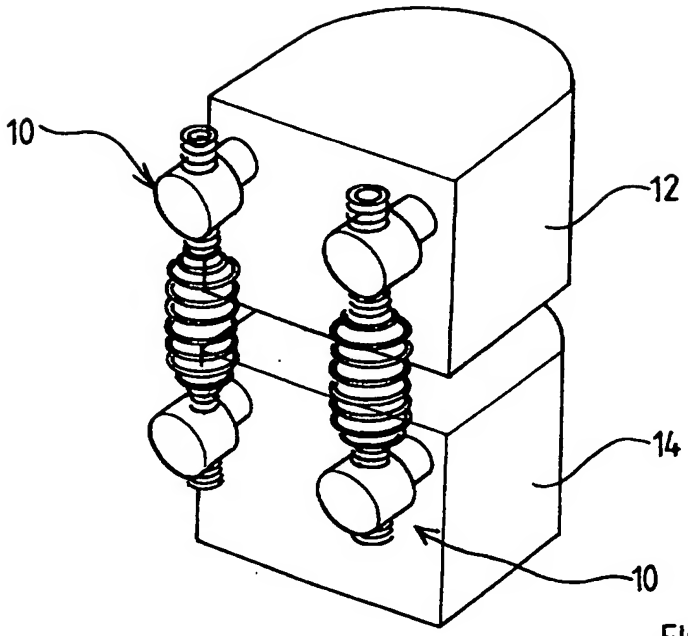


FIG 5

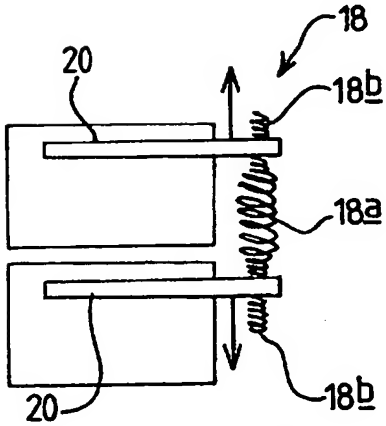


FIG 6a

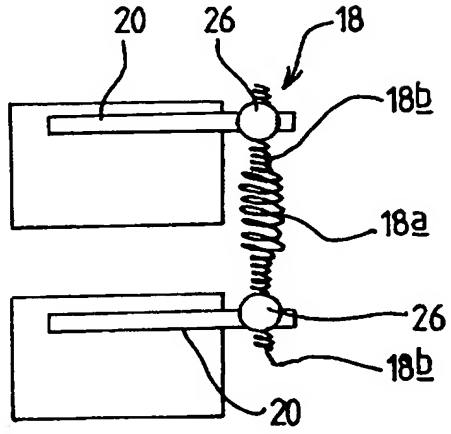


FIG 6b

FIG 7a

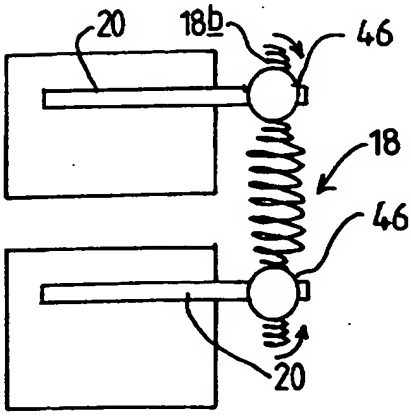
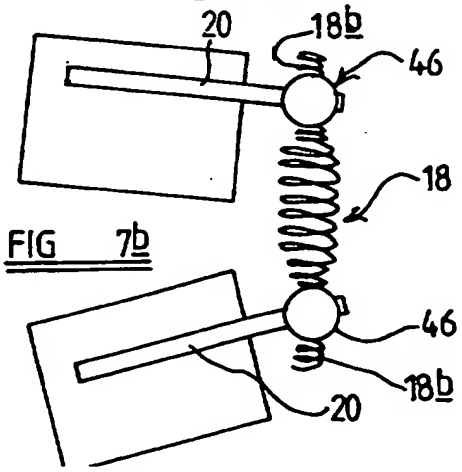


FIG 7b



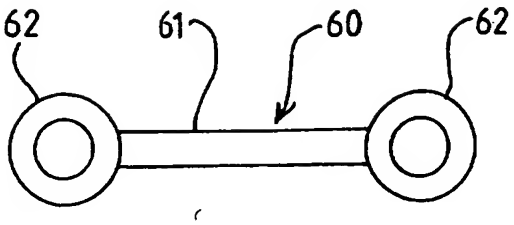


FIG 8a

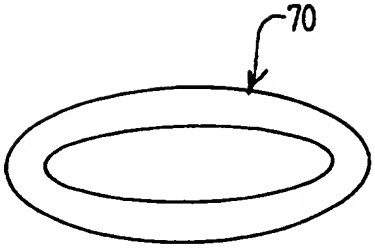


FIG 8b

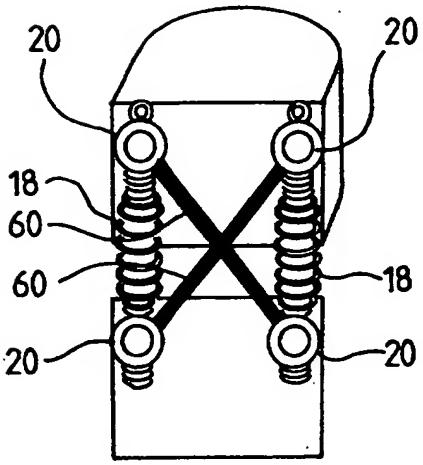


FIG 9

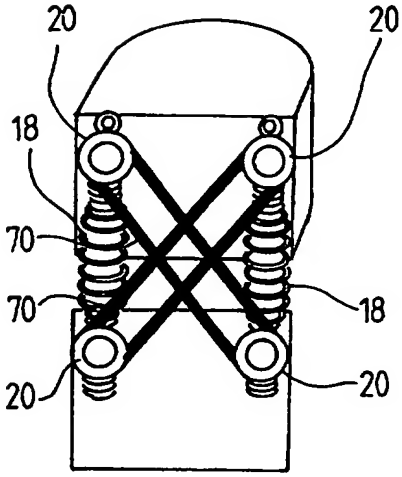


FIG 10

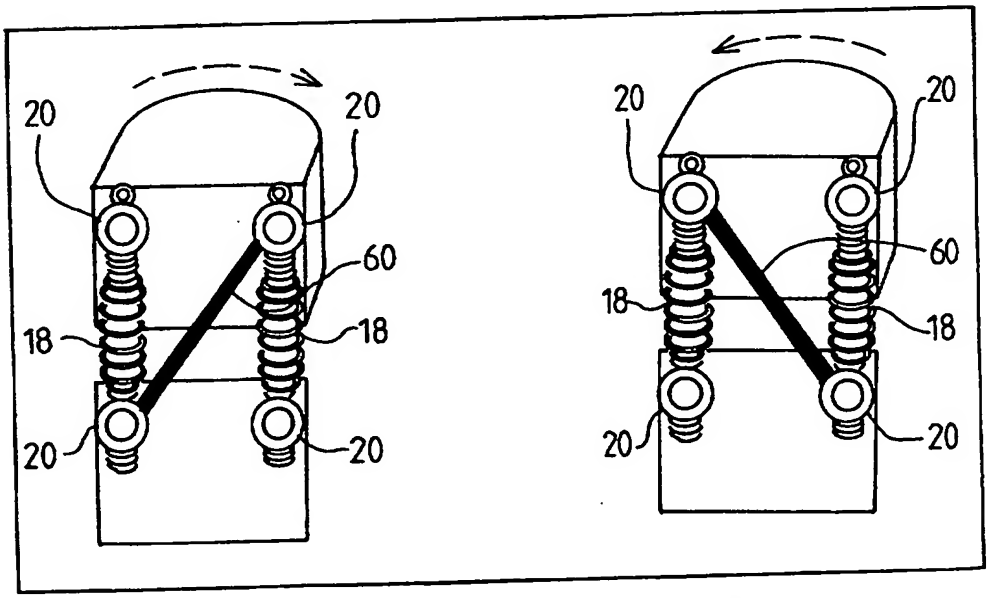


FIG 11

PATENTS ACT 1977

A10418GB-DMW

Title: An assembly for soft stabilisation of vertebral bodies of the spine

Description of Invention

The invention relates to an assembly for soft stabilisation of vertebral bodies of the spine of the kind which is secured to the adjacent vertebral bodies by pedicle screws, and in particular although not exclusively to such an assembly for stabilisation of two adjacent vertebral bodies.

The present invention is applicable for the treatment of a range of spinal pathologies including low back pain and deformity.

A number of stabilisation techniques have previously been described for the treatment of low back pain. The lower, or lumbo-sacral region of the human spine consists of five lumbar vertebrae located above the large triangular bone called the sacrum. Between adjacent lumbar vertebrae are inter-vertebral discs (IVD) which have a complex structure, with a central jelly like nucleus pulposus and a peripheral rim of tough fibrous layers, the annulus fibrosus. Each lumbar vertebra is made up of a vertebral body, with upper and lower end plates, which contact the IVD's, and facet joints located posteriorlly. Movement in the lumbo-sacral spine occurs in the IVD's at the front and at the facet joints at the rear. Thus, the IVD's and the facet joints provide stability of the motion segment between adjacent vertebra. However, they also transfer load from one vertebra to the next, and it is estimated that the IVD bears approximately 80% of the load and the pair of facet joints at the rear bear approximately 20% of the load. A normal IVD can distribute the load uniformly across the surface of the end plate of the vertebral body. However, when the IVD and/or the facet joints are damaged or degenerate this can lead to

instability of the motion segment between adjacent vertebra and commonly to low back pain. It is considered that the pain can be caused by abnormal movement, and/or by abnormal distribution of load across the end plates of the vertebrae.

Conventional treatment of low back pain is to limit movement between adjacent vertebrae, typically by fusing the adjacent vertebrae together. However, fusion has a high failure rate for pain relief.

More recently treatment with prosthetic IVD's has been tried in an attempt to preserve the normal movement and normal load bearing of the inter-vertebral joints. However, thus far the results are no better than in fusion of adjacent vertebrae.

An alternative approach is that of "soft stabilisation" which aims to prevent abnormal motion in painful motion segments of the lumbo-sacral spine, but to save as much as possible of the normal motion. Several methods of soft stabilisation have been described in the literature, but only two are currently in use.

The Graf ligament system consists of a fabric ligament secured across pedicle screws located in the adjacent vertebrae. Typically two such ligaments are located across each motion segment, one to each side of the spinous processes on the rear of the spine. This system creates lordosis (curvature of the spine, convex forwards) and restricts the movement of the motion segment between the vertebrae concerned, but it also increases the load at the posterior part of the IVD. In one such system (Dynesys-Sulzer, as described in European patent application published under No. EP 0 669 109) excessive lordosis is prevented by a cylinder embracing the ligament between the pedicle screws. However, actual distraction of the disc space can only be achieved by producing flexion of the motion segment. This results in a kyphotic (convex backwards) segment, and kyphotic segments in the lumbo-sacral spine can

produce back pain. Hence, there are significant problems with the use of such a system.

Another soft stabilisation system which is in the process of development is a fulcrum assisted soft stabilisation system (FASS) which is described in International patent application No. PCT/CH99/00612. In this system the compressing effect of the ligament found in the Graf ligament system is converted into a distraction effect by the use of a fulcrum bridging between the pedicle screws, and located between the ligament and the spine. This system can unload the IVD in forward flexion but not in extension. However, it is known from the literature that the IVD is loaded both in flexion and extension and the facet joints are specifically loaded in extension. Hence, this system also is expected to suffer from disadvantages.

None of the soft stabilisation systems described above therefore addresses the important aim of addressing uniform IVD distraction to create a normal loading pattern across the end plates of the vertebrae, both in flexion and extension. An Alternative soft stabilisation system which addresses that aim, and mitigates the problems described above is described in the applicant's copending UK patent application No. 0114783.4.

The soft stabilisation systems described above serve the basic requirements of unloading the disc and creating or maintaining lordosis as appropriate. However, all such systems restrict motion of the spinal segment, and in general the greater the unloading of the disc the greater the degree of stiffness imparted to the spinal segment. However, whilst the stiffness reduces the flexibility of the segment in flexion/extension and in lateral bending, it has least effect against rotation.

It is an aim of the present invention to provide a further alternative soft stabilisation system which, whilst unloading the disc and maintaining lordosis, has minimal effect in restriction of flexion/extension and lateral bending and

greater effect in restriction of rotation of the spinal segment, and/or to correct spinal deformity.

According to a first aspect of the present invention there is provided an assembly for soft stabilisation of vertebral bodies of the spine comprising a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises a helical spring member having first and second ends and a pair of fixation mechanisms for securing the first and second ends of the helical spring member to the pair of pedicle screws.

Preferably the helical spring member comprises an active central portion between first and second passive end portions.

Conveniently the active central portion of the helical spring member comprises spaced apart coils of a first diameter, and the passive end portions of the helical spring member comprise closely adjacent coils of a second diameter, the second diameter being smaller then the first diameter.

The second diameter may be between two thirds and one third of the first diameter.

The second diameter may be substantially half the first diameter.

Preferably the spring member is formed from wire. The wire may have a diameter in the range 1 to 6 mm, or in the range 2 to 5 mm. The wire may be round in cross section, or alternatively may be square or rectangular in cross section. The wire is preferably titanium or stainless steel.

The assembly may further include a sleeve covering the helical spring member.

Typically the sleeve is made of plastics material.

The assembly may further comprise an elastic member securable to the heads of a pair of pedicle screws.

According to a second aspect of the invention there is provided an assembly for soft stabilisation of vertebral bodies of the spine may further

comprise a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises an elastic member having first and second ends; and a pair of fixation mechanisms for securing the first and second ends of the elastic member to the pair of pedicle screws.

The elastic member may comprise an active central portion and loops at each end for securing to the pedicle screws. Alternatively the elastic member may comprise a continuous band.

The assembly may be for stabilisation of two adjacent vertebral bodies of the spine.

An embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a schematic illustration of an assembly according to the invention in use;

Figure 2 illustrates a helical spring member for incorporation in the assembly of Figure 1;

Figure 3 illustrates a fixation mechanism suitable for use in the assembly of Figure 1;

Figure 4 illustrates an alternative fixation mechanism;

Figure 5 illustrates schematically a pair of assemblies according to the invention in use, from perspective angle;

Figure 6 illustrates schematically how the assembly of Figure 1 can be used for distraction of the motion segment;

Figure 7 illustrates schematically how the assembly of Figure 1 can be used to create lordosis;

Figure 8 illustrates two forms of elastic member for inclusion in assemblies according to the invention;

Figure 9 illustrates the elastic member of Figure 8a in use;

Figure 10 illustrates the elastic member of Figure 8b in use; and

Figure 11 illustrates the use of assemblies according to the invention for correction of the spinal deformity.

Referring first to Figure 1, an assembly 10 for the stabilisation of two adjacent vertebral bodies 12, 14 of the spine is illustrated schematically. The vertebral bodies 12, 14 are separated by an inter-vertebral disc 16 which has a nucleus pulposus 16a and a fibrous outer-annulus, called the annulus fibrosus, 16b. For simplicity the facets joints have been omitted from the posterior of the vertebral bodies 12, 14.

The assembly 10 comprises a helical spring member 18, illustrated in Figure 2, which has a central active portion 18a and first and second passive end portions 18b extending outward therefrom. The active portion 18a of the helical spring member 18 comprises spaced apart coils whilst the first and second passive end portions 18b comprise tighter closely adjacent coils. The coils of the active portion 18a are of a first diameter, and the coils of the first and second end portions 18b are a second diameter, the first diameter being substantially greater than the second diameter. Typically, the second diameter will be in the region of $^1/_3$ to $^2/_3$ of the first diameter, although it may be substantially ½ the first diameter. The helical spring member 18 is covered by a sleeve 18c made of plastics material or some other inert material which is acceptable for implantation into the body. This will prevent tissue being trapped between the coils, or indeed growing inbetween the coils of the helical spring member 18.

The assembly 10 further comprises a pair of pedicle screws 20 each of which comprises a threaded shaft portion 20a with a tapering first end 20b and a head portion 20c with a second end 20d.

The assembly 10 is illustrated in Figure 1 in position secured to a pair of adjacent vertebral bodies 12, 14 with the threaded shaft portions 20a of the pedicle screws 20 inserted into the vertebral bodies 12, 14 to the same side of

the spine. The helical spring member 18 is secured to the heads 20c of each of the pedicle screws 20 by a fixation mechanism as appropriate. An example of a fixation mechanism will now be described.

Referring now to Figure 3 an example of a fixation mechanism 26 is illustrated, the mechanism being known in the prior art. The head 20c of the pedicle screw 20 is shown with a particular form. It comprises a slot 30 which provides the dual purpose of accepting the blade of a screw driver for insertion of the pedicle screw 20 into a vertebral body, and for receipt of the inactive portions 18b of the spring member 18. The head 20c further comprises adjacent its second end 20d, and around the upper part of the slot 30, a threaded portion 32. The fixation mechanism 26 further comprises a sleeve member 34 and threaded nut 36.

The fixation mechanism 26 is shown assembled in Figure 3b. Once the screw 20 has been inserted into the vertebral body one inactive portion 18b of the spring member 18, is located in the slot 30. The sleeve member 34 is then placed over the head 20c of the pedicle screw 20, and the nut 36 screwed down onto the threaded portion 32 to retain the spring member 18 in place. The fixation mechanism 26 may further include a check nut (not shown), as is known in the prior art, to further secure the mechanism together and to reduce the possibility of it loosening over time.

It should be appreciated that the fixation mechanism 26 is one example of many options which would be available, and any appropriate fixation mechanism may be used. A modified form of fixation mechanism is illustrated simplistically in Figure 4. In this fixation mechanism 46 a head portion 48 may be rotated relative to the pedicle screw 20 and fixed such that slot 50 is provided at a desired angle to the pedicle screw 20. Use of the fixation mechanism 46 provides the ability to secure the helical spring member 18 to adjacent vertebra in such a manner as to exert forces on the motion segment to create lordosis or kyphosis.

Referring now in particular to Figure 2, a helical spring member 18 for incorporation into the assembly 10 is illustrated more clearly. Figure 2a shows the helical spring member 18 from Figure 1, with the sleeve 18c partially cut away to show the helical spring member 18 more clearly. In Figure 2b the sleeve 18c completely covers the helical spring member 18.

The helical spring member 18 is made from titanium or stainless steel wire, each spring member being formed from a single piece. The wire will typically have a diameter in the range 1 to 6mm, but preferably in a range of 2 to 5mm. The wire may be round in cross-section or may be of other forms e.g. square, rectangular, or oval in cross section.

Helical spring member 18 designed to be used between adjacent vertebral bodies, have an overall length in the range 20mm to 65mm, but preferably in the range 25mm to 60mm.

Referring now in particular to Figure 5, a pair of assemblies 10 according to this invention are shown secured to a pair of adjacent vertebral bodies 12, 14. This is the manner in which the assembly 10 will generally be used, with one assembly 10 applied to either side of the vertebral bodies on the posterior aspect of the spine.

Referring now to Figure 6 one effect of use of the assemblies 10 is illustrated. In Figure 6, it can be seen that unloading of the inter-vertebral disc can be achieved by separation of the pedicle screws 20, or distraction of them, along the passive end portions 18b of the helical spring member 18 before securing the helical spring member 18 to the pedicle screws 20 using the fixation mechanisms 26. Thus the assembly 10 will hold the vertebral bodies 12, 14 further apart, unloading the disc, yet still permit some movement which is relatively normal.

Referring now to Figure 7, another effect of the use of the assemblies 10 is illustrated. In particular, it can be seen that lordosis of the motion segment can be achieved by controlling the angle of fixation of the inactive portions 18b

of the helical spring member 18 with respect to the pedicle screws 20 using the fixation mechanisms 46.

The assembly 10 may also comprise elastic members 60 as illustrated in Figure 8a, or elastic members 70 as illustrated in Figure 8b. Elastic member 60 comprises an active central portion 61 and loops 62 at each end for connection to the head ends of the pedicle screws 20 in the manner shown in Figure 9. Elastic member 70, being a continuous loop of material can simply be secured around the head ends of the pedicle screws 20 as shown in Figure 10. In such assemblies 10 the pedicle screws may appropriately have specific provision (not shown) for receipt of the elastic members. Where two elastic members are used crossed across the motion segment, in combination with two assemblies as previously described, as in Figures 9 and 10, it will control the rotation of the vertebral bodies in relation to each other in either direction. Such an arrangement is for the treatment of low back pain.

For the treatment of deformity, the elastic members 60, 70 are used to resist rotation of the motion segments in either clockwise or anticlockwise directions as required, and as illustrated in Figure 11. Thus for the treatment of deformity a single elastic member will generally be used in each motion segment being treated, connecting a pedicle screw inserted on one side of the upper vertebra and a pedicle screw inserted on the opposite side of the lower vertebra. The elastic member may be used on its own or in combination with a helical spring member.

It is anticipated that a combination of helical spring members 18 and/or elastic members 60, 70 may be used to correct a range of deformities. For example, use of one helical spring member on one side of a motion segment will try to bend the spine laterally, whilst a single elastic member crossing across the motion segment will tend to rotate the spine in one direction. Hence, a combination of helical spring members 18 and/or elastic members 60, 70 may be used in several motion segments to correct scoliosis of the spine.

It is anticipated that the assemblies according to the invention will normally be implanted incorporating both helical springs and elastic members. However, the exact form of assembly used for any particular patient will be selected by the surgeon performing the operation to provide the appropriate treatment for the condition being treated. In some cases this will mean implantation of the assembly incorporating just one or more helical springs, and no use of elastic members, or just one or more elastic members and no use of helical spring member.

The exact design of helical spring members for use in a particular case will depend on a large number of factors. These will include the sizes of the vertebral bodies, the number of motion segments requiring stabilisation, and the particular condition being treated. Similar considerations apply to the form of elastic members 60, 70 which will be chosen to provide the required forces.

In the present specification "comprises" means "includes or consists of" and "comprising" means "including or consisting of".

The features disclosed in the foregoing description, or the following claims, or the accompanying drawings, expressed in their specific forms or in terms of a means for performing the disclosed function, or a method or process for attaining the disclosed result, as appropriate, may, separately, or in any combination of such features, be utilised for realising the invention in diverse forms thereof.

Claims

1. An assembly for soft stabilisation of vertebral bodies of the spine comprising a pair of pedicle screws each having a threaded shaft with a tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises:

a helical spring member having first and second ends; and

a pair of fixation mechanisms for securing the first and second ends of the helical spring member to the pair of pedicle screws.

2. An assembly according to claim 1 characterised in that the helical spring member comprises an active central portion between first and second passive end portions.

3. An assembly according to claim 2 characterised in that the active central portion of the helical spring member comprises spaced apart coils of a first diameter.

4. An assembly according to claim 3 characterised in that the passive end portions of the helical spring member comprise closely adjacent coils of a second diameter, the second diameter being smaller then the first diameter.

5. An assembly according to claim 4 characterised in that the second diameter is between two thirds and one third of the first diameter.

6. An assembly according to claim 5 characterised in that the second diameter is substantially half the first diameter.

7. An assembly according to any one of the preceding claims characterised in that the helical spring member is formed from wire.

8. An assembly according to claim 7 characterised in that the wire has a diameter in the range 1 to 6 mm.

9. An assembly according to claim 8 characterised in that the wire has a diameter in the range 2 to 5 mm.

10. An assembly according to any one of claims 7 to 9 characterised in that the wire is round in cross section.

11. An assembly according to any one of claims 7 to 10 characterised in that the wire is titanium or stainless steel.

12. An assembly according to any one of the preceding claims characterised in that it further includes a sleeve covering the helical spring member.

13. An assembly according to Claim 12 characterised in that the sleeve is made of plastics material.

14. An assembly according to any one of the preceding claims characterised in that it further comprises an elastic member securable to the head ends of a pair of pedicle screws.

15. An assembly for soft stabilisation of vertebral bodies of the spine comprising a pair of pedicle screws each having a threaded shaft with a

tapering first end for introduction into a vertebral body and a head portion with a second end, characterised in that it further comprises:

an elastic member having first and second ends; and

a pair of fixation mechanisms for securing the first and second ends of the elastic member to the pair of pedicle screws.

16. An assembly according to Claim 14 or 15 characterised in that the elastic member comprises an active central portion and loops at each end for securing to the pedicle screws.

17. An assembly according to Claim 14 or 15 characterised in that the elastic member comprises a continuous band.

18. An assembly according to any one of the preceding claims characterised in that it is for stabilisation of two adjacent vertebral bodies of the spine.

19. An assembly for the stabilisation of two adjacent vertebral bodies of the spine substantially as hereinbefore described with reference to the accompanying drawings.

20. Any novel feature or novel combination of features described herein and/or in the accompanying drawings.

Application No: GB 0124291.6
Claims searched: 1-14

Examiner: Dr Jonathan Corden
Date of search: 27 March 2003

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X	1, 7, 11	US 5733284 A	(MARTIN) see figs, column 2 lines 12-29, column 3 line 50 - column 5 line 14 and column 6 lines 1-24
X	1, 7, 11	US 5423816 A	(LIN) see figs, column 2 line 28 - column 3 line 16
X	1	US 5180393 A	(COMMARMOND) see figs, column 1 lines 1-3 and 18-35, column 2 lines 6-18, column 3 lines15-16
A, E	1, 2, 7-11	WO 02/102259 A2	(SENGUPTA et al) see figs, abstract, page 3 line 9 - page 4 line 24 and claims especially
A	-	WO 01/45576 A1	(SYNTHES)
A	-	GB 2269753 A	(SURGICRAFT)
A	-	EP 0669109 A	(PROTEK) and also WPI Abstract Acc. No. 1995-294163

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[V]:

A5R

Worldwide search of patent documents classified in the following areas of the IPC[7]:

A61B

The following online and other databases have been used in the preparation of this search report:

EPODOC, WPI, PAJ